



December 20, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, MD 20852

Docket No. 2003N-0312

To Whom It May Concern:

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the proposed Animal Feed Safety System (AFSS). Solicitation for comment is from the Federal Register, March 31, 2004. AAFCO is an international association with membership consisting largely of state feed control officials responsible for administration of state laws, rules, and portions of the Food, Drug and Cosmetic Act pertaining to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets. All fifty states, Puerto Rico, Canada and Costa Rica are members of AAFCO.

AAFCO is supportive of the FDA proposed comprehensive concepts and elements of an animal feed safety system. However, certain clarifications and modifications may improve the understanding of the intent of AFSS and the extent of the scope of authority and oversight.

**Comprehensive Section.** These concepts must be clear in identifying which sectors of the feed manufacturing community and what feed and feed components are targeted under this authority and oversight. Is the intent to include on-farm feed mixers/mills? If so, this should be indicated through an introductory preamble or included in the language of the first and third concepts. It should also include, but not be limited to all ingredients, premixes, intermediates, supplements, nutraceuticals and finished feeds. This may also require expanded language in the first concept.

The second concept includes that ingredients be approved and/or recognized, as established by a regulatory agency or entity whose members are charged with a responsibility of enforcing laws regulating the production, labeling, distribution, or sale of animal feeds. It should also require that those ingredients be used for approved and/or recognized purposes. Is approval or recognition from an established regulatory agency meant to include a "State" and/or "International" agency or entity such as the EU? This needs further clarification.

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The fourth concept addresses the flexibility of AFSS to be process or product oriented, depending on the situation. The existing language should be expanded to demonstrate the differences between the two and examples of application.

The sixth concept expresses the absolute, “cover all known hazards, and be applicable to hazards not yet identified.” Absolutes are not recommended and the word “all” should be removed.

Overall, the comprehensive definition and concepts did not seem to address or include the international aspects of feed manufacturing, distribution and feed safety. Other agencies that could play a role in the animal feed manufacturing and distribution arena should be included, such as the Department of Transportation, United States Department of Agriculture and other human and animal health departments.

**Risk-based definition.** The proposed definition is difficult to understand and needs revision. The sentence structure is clumsy and does not flow well. Consider changing the order to first address “risk” and secondly, “risk based.” How “risk-based” will be used should not be included in the definition, but provided in another sentence or bullet. Other issues of consideration: how to determine deleterious amounts; are the risks science-based; how to prioritize risks and do the regulations currently make risk-based decisions and how?

**Elements.** In addition to the existing proposed elements, an animal feed safety system should include provisions to:

- #1 Incoming materials –assure incoming materials are approved/recognized and are for approved/recognized uses; adequate label review; supplier selection and qualification based on internal specifications for hazard identification for incoming materials and expiration considerations (first in-first out). Storage bins should be approved and appropriate for the intended use.
- #2 Processing/Manufacture – assure adequate, defined processing steps to ensure animal feed safety; identification/recall ability through required lot numbers/production codes for all feed products (including feed ingredients and finished feeds). Consideration should be given to relocating or reiterating section 1.b. into section 2 and for language to address appropriate storage of product “after” manufacturing in section 2 or additional language in section 1.d.
- #3 Record Keeping – require records for all essential elements of the animal feed safety system.
- #4 Distribution/Transportation/Feeding – assure this element applies to incoming feed ingredients, feed components and finished feeds, should include incoming ingredient transportation and product log; use of any 3<sup>rd</sup> party inspection for transportation must meet all regulations required by regulatory officials and specifications of receiver of materials. Review AAFCO Best Management Practices Guidance Document for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients (AAFCO OP, Page 207, Section IV and VIII).

- #5 Inspection/Audit/Corrective Action – separate the maintenance of the complaint file from the review, evaluation and implementation of the corrective actions taken as a result of the complaint. This could be accomplished by splitting these areas into two different issues.
- #6 Responsibilities – assure periodic review of written SOP's by a responsible party.
- #7 Training – assure adequate record keeping of employee training and evaluation and periodic review of those records by a responsible party.

Currently, AAFCO is in the process of developing model feed regulations for all feed and feed ingredient manufacturers, including on-farm mixer/feeders. It is hoped that the outcome of the AAFCO efforts will be harmonious with the AFSS and that federal and AAFCO resources are not wasted on duplicative efforts.

In the future, in light of the increasing role of state regulatory agencies involved in protection of the human and animal food supply, AAFCO hopes to see consideration of the following:

- Continued and improved sharing of information and interagency communication between state and federal agencies.
- Continued efforts to involve DFSR in the information and interagency communication, including the Animal Feed Safety System (AFSS).
- Increased support and resources for state training for enforcement and inspections.
- A means of factoring risk to humans and animals into the areas mentioned above.

Sincerely,



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